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|-------------------------------|------------------------|---------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 10/686,918             | MARCUM, FRANK D.    |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | EVERETT WHITE          | 1623                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communications (telephonic interview) dated June 9, 2004.
2. ☒ The allowed claim(s) is/are 1-10 and 21-36.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                                     |                                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)                                                    | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>June 9, 2005</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                             |
|                                                                                                                     | 9. <input type="checkbox"/> Other _____.                                                                         |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with J.W. Seanor on June 9, 2005.

The application has been amended as follows:

Claims 1, 3-5 and 10 have been amended as follows:

1. (Currently Amended) A composition adapted for parenteral ~~intra-articular~~ administration for the treatment ~~and/or prevention of~~ traumatic synovitis and/or damaged articular cartilage of a diarthrodial joint in man or in animals, the composition comprising therapeutic amounts of: chondroitin sulfate; N-acetyl D-glucosamine; ~~and~~ hyaluronan and in the absence of a separate analgesic agent.

3. (Currently amended) The composition of claim 2, wherein the suitable chondroitin sulfate is ~~CS4 chondroitin sulfate~~ chondroitin 4-sulfate.

4. (Currently Amended) The composition of claim 2, wherein the suitable chondroitin sulfate is ~~CS6 chondroitin sulfate~~ chondroitin 6-sulfate.

5. (Currently Amended) The composition of claim 2, wherein the suitable chondroitin sulfate is a mixture of ~~CS4 chondroitin sulfate and CS6 chondroitin sulfate~~ chondroitin 4-sulfate and chondroitin 6-sulfate.

10. (Currently Amended) A composition adapted for parenteral administration for the treatment ~~and/or prevention of~~ traumatic synovitis and/or damaged articular cartilage of a diarthrodial joint in man or in animals, the composition consisting essentially of

therapeutic amounts of; chondroitin sulfate; N-acetyl D-glucosamine; and hyaluronan  
and in the absence of a separate analgesic agent.

Claims 11-20 have been canceled.

Claims 21, 25, 29 and 33 have been amended as follows:

21. (Currently Amended) A method for the treatment ~~and/or prevention~~ of damaged articular cartilage of a diarthrodial joint in man or in animals, comprising administering to a man or animal in need thereof, a therapeutically effective therapeutic amount of a composition comprised of chondroitin sulfate; N-acetyl D-glucosamine; and hyaluronan and in the absence of a separate analgesic agent.

25. (Currently Amended) A method for the treatment ~~and/or prevention~~ of damaged articular cartilage of a diarthrodial joint in man or in animals, comprising administering to a man or animal in need thereof, a therapeutic therapeutically effective amount of a composition consisting essentially of chondroitin sulfate; N-acetyl D-glucosamine; and hyaluronan and in the absence of a separate analgesic agent.

29. (Currently Amended) A method for the treatment ~~and/or prevention~~ of a damaged synovial membrane, traumatic synovitis, in man or in animals, comprising administering to a man or animal in need thereof, a therapeutically effective therapeutic amount of a composition comprised of chondroitin sulfate; N-acetyl D-glucosamine; and hyaluronan and in the absence of a separate analgesic agent.

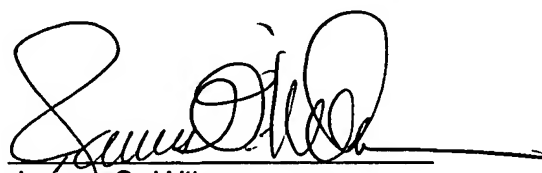
33. (Currently Amended) A method for the treatment ~~and/or prevention~~ of damaged synovial membrane, traumatic synovitis, in man or in animals, comprising administering to a man or animal in need thereof, a therapeutically effective therapeutic amount of a composition consisting essentially of chondroitin sulfate; N-acetyl D-glucosamine; and hyaluronan and in the absence of a separate analgesic agent.

The following is an examiner's statement of reasons for allowance:

During a telephonic interview with Applicant Attorney, Mr. J.W. Seanor, on June 9, 2005, it was agreed to amend the independent claims in the application to overcome the rejection of claims over the Hammerly publication (US 2001/0046971 A1) by indicating that the claimed compositions and the compositions used in the methods thereof comprises the recited components thereof "and in the absence of a separate analgesic agent".

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

  
E. White

  
James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600